UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,498	06/01/2001	Adilson Leite	FAPESP 203	8814

24972 7590 05/04/2006

FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,498	LEITE ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' petition filed 23 September 2004 to withdraw this application from issue pursuant to 37 C.F.R. § 1.313©(2) following payment of issue fee in favor of a "Request or Continued Examination (i.e., RCE)" in compliance with 37 C.F.R. §1.114 is acknowledged and entered.

2. In view of the decision by Ms. Sherry D. Brinkley of the Office of Petitions mailed on 29 September 2004 on the petition cited *supra*, and filing of an RCE on 23 September 2004, action on the RCE follows.

3. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 23 September 2004 concurrent with a petition to withdraw this application from issue pursuant to 37 C.F.R. § 1.313©(2) following payment of issue fee. Since, as indicated *supra,* said petition has been granted by he Office of Petitions, this application is eligible for continued examination under 37 CFR §1.114. The fee set forth in 37 CFR §1.17(e) has been timely paid, the previous Office action mailed 16 March 2004 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed 23 September 2004 has been entered. Accordingly an RCE has been established and the action on RCE follows.

4. The Art Unit Location of your instant application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is changed to Art Unit 1655.

5. Your instant application under prosecution at the USPTO has been assigned to Dr. Kailash C. Srivastava in ART Unit 1655. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

6. To facilitate expeditious prosecution of this application and prevent any potential loss of documents during communication with this office, Examiner suggests that applicants write the application number and attorney docket number in the header for each page of any future communication/correspondence with this office.

Claims Status

7. Claims 1-29 are pending.

8. Claims 1 and 24 have been amended

Election/Restriction

9. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I – Claims 1-4 drawn to a method to identify an antimicrobial peptide that binds to infective microorganisms, classified under Class 435, Subclass 32, for example.
- Group II – Claims 6-7 and 29 drawn to a composition comprising a peptide having amino acid sequence set forth in SEQ ID NO; 1 or a conservative variant of said SEQ ID No: 1, classified under Class 530, Subclass 300, for example.
- Group III – Claim 8 drawn to a peptide analog, said peptide analog having antimicrobial activity, classified under Class 424, Subclass 150.1, for example.
- Group IV – Claim 10 drawn to an isolated nucleic acid, classified under Class 435, Subclass 6, for example.
- Group V – Claims 11-12 drawn to an expression vector, classified under Class 435, Subclass 320.1, for example.
- Group VI – Claims 13-16 drawn to a host cell, classified under Class 435, Subclass 320.1, for example.
- Group VII– Claims 17-23 drawn to a method to prevent or inhibit growth or decrease viability of a microorganism comprising contacting said microorganism with an effective quantity of a polypeptide, classified under Class 435, Subclass 800, for example.
- Group VIII – Claims 24-28 drawn to a method to treat an organism infected with a pathogenic microorganism, classified under Class 514, Subclass 2, for example.

Linking Claims

10 Claims 5 and 9 are linking claims, wherein Claim 5 links inventions in Groups II-III and Claim 9 links inventions in Groups IV-V. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claims, identified above. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. §121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131- 32 (CCPA 1971). See also MPEP §804.01.

Inventions are Independent or Distinct

11. Inventions in Groups I, VII and VIII are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group I is a method to identify an antimicrobial composition, whereas method in Group invention VII is to prevent or decrease the viability of a microorganism. Thus, inventions in each of Groups I VII and VIII methods have different steps and different effect and therefore, those inventions cannot be practiced together.

Inventions in Groups I, VII and VIII are unrelated to inventions in Groups IV-VI because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods and products at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group I is a method to identify an antimicrobial composition, whereas composition in Group VI is a host cell to produce a peptide. Thus, inventions in each of Groups I, VII and VIII methods and composition inventions in Groups IV-VI have different application and effect and therefore, those inventions cannot be practiced together.

Inventions in Groups II-III are related to each other as combination/ sub-combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the sub-combination as claimed for patentability, and (2) that the sub-combination has utility by itself or in other combinations [MPEP §806.05(c)]. In the instant case, the combination (the isolated peptide) does not require the particulars of the sub-combination (i.e., peptide analog) as claimed for patentability because the combination, by itself would be patentable even if the sub-combination was known and non-obvious, assuming that the prior art does not teach or suggest the presence of the additional ingredients recited in the combination claims. The sub-combination has utility of its own because it will be applicable for not only controlling the microbial infection but also control microbial infestation to a food or an item that is susceptible to microbial infestation.

Inventions in Groups II and III are related to Inventions in Groups I, VII and VIII as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. For example, the method of invention encompassed in Group VII invention can be accomplished with a number of products available in he market place as both over the counter as well as prescription medications (e.g., erythromycin ointment). Similarly, for example the peptide of invention II also has application in the food/feed industry to retard microbial growth or infestation.

Invention in Groups IV-VI are related to invention in Groups II and III as products and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. For example, the products in inventions II-III may also be produced through fermentation or peptide synthesis procedures known to one skilled and the procedures described in the literature. Similarly, for example the isolated nucleic acid, the vector and the host cell IN invention Groups IV-VI are applicable to produce any product (e.g., a tagged amino acid or a blood protein (e.g., erythropoietin)).

Inventions in Groups IV-VI are related to each other as combination/ sub-combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the sub-combination as claimed for patentability, and (2) that the sub-combination has utility by itself or in other combinations [MPEP §806.05(c)]. In the instant case, the combination (isolated nucleic acid) does not require the particulars of the sub-combination (e.g., the particular vector or host cell) as claimed for patentability because the combination, by itself would be patentable even if the sub-combination was known and non-obvious, assuming that the prior art does not teach or suggest the presence of the additional ingredients recited in the combination claims. The sub-combinations have utility of their own because they will be applicable for expressing any nucleic acid sequence either with combination of same vector and host cell or a different vector with same host cell or same vector in a different host cell.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. For example the search for invention in Group I would require a search for peptides that inhibit microbes, the search in group II on the other hand would require an antimicrobial peptide or

analog hereof having the properties of SEQ. ID I. Similarly, different search strategies need to be formulated for searching each of he inventions in Groups IV-VIII. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., Class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

12 Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141.In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain

the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1655
(571) 272-0923

April 26, 2006

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200